



UNITED STATES PATENT AND TRADEMARK OFFICE

9
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,783	04/21/2005	Hans Schreier	05/063	6308
30008	7590	12/14/2007		
GUDRUN E. HUCKETT DRAUDT SCHUBERTSTR. 15A WUPPERTAL, 42289 GERMANY			EXAMINER LAM, ANN Y	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 12/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,783

Applicant(s)

SCHREIER ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's attorney, Grudun Hockett, submitted a letter, received on October 15, 2007, and also placed a telephone message on December 12, 2007 that the Office action of October 4, 2007 is missing the body of the action. Examiner acknowledges that it appears that only the front page and the notice of reference cited were mailed. Thus, the present Office action is submitted to include the body of the action and to re-set the period for reply based on the new mailing date, as requested by Applicant's attorney.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8 and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown, 2003/0229514.

Brown recites in claim 57, a portable apparatus comprising a housing that is compact to be hand-held and carried by a patient, a health condition parameter measurement apparatus integrated with the housing for testing a health condition parameter and generating health condition parameter data representative of a health condition parameter value of the patient, a compartment for holding a supply of medicine within the housing and which permits the medicine to be arbitrarily withdrawn from the housing, among other features. In claim 58, Brown recites that the health condition is diabetes, health condition parameter including blood glucose, the health condition parameter value including blood glucose level, and the supply of medicine including an insulin infusion device, the medicine including insulin, and the health condition parameter measurement apparatus being a blood glucose meter. In claim 62, Brown recites that the apparatus further comprises a patient interface of the blood glucose meter coupled to the housing, and in claim 63, the insulin infusion device comprising a syringe. In the specification, Brown discloses a monitoring device (28) designed to produce measurements of a physiological condition of a patient. Brown teaches that examples of suitable monitoring devices include blood glucose meters for measuring blood glucose concentrations in diabetes patients and that such monitoring devices are well known in the art (paragraph 0005).

As to claim 8, the insulin is equivalent to the medicament recited by Applicants, and the monitoring device (disclosed as element 28, and recited as a health condition parameter measurement apparatus in claim 57, for example a blood glucose meter in claim 62) is equivalent to Applicants' diagnostic indicator

system. Thus the apparatus claimed by Brown is equivalent to Applicants' medicament/dosimeter combination package.

As to claims 11-12, the syringe is equivalent to Applicants' injector, and can adjust the therapy since the amount injected by the syringe can be adjusted.

As to claim 13, Brown teach that the apparatus is hand-held and carried by a patient (claim 57).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, 2003/0229514, in view of Phillips et al., 5,843,692.

Brown discloses the invention substantially as claimed (see above). More specifically, Brown teaches that the health condition parameter measurement apparatus (or monitoring device 28) can be a blood glucose meter patients and that such monitoring devices are well known in the art (paragraph 0005). However, Brown does not give more specifics about the blood glucose meter, and presumably contemplates using known blood glucose meters. Therefore, Brown does not specifically disclose that the diagnostic indicator system is

comprised of a strip impregnated with a chemical (as recited in Applicants' claim 9), nor that the detection can be visual or spectrophotometric (as recited in Applicants' claim 10).

Phillips et al. however teach a blood glucose meter that has these elements and characteristic. Phillips et al. teach a test strip (10) on a scanning machine (60) (col. 11, lines 9-10). The test strip has chemical reagents that will form light-absorbing reaction product (col. 6, lines 5-6 and col. 7, lines 10-55). The measuring instruments is a reflectance spectrophotometer to read reflectance (col. 8, lines 29-31.) The disclosed device is a meter that measures blood glucose concentrations (col. 14, lines 47-65.) The test strip (10) and scanning machine (60) together are equivalent to Applicants' diagnostic indicator system.

While Brown teaches that the measuring apparatus can be a blood glucose meter and that such devices are well known in the art but does not give a specific example of a blood glucose meter, the skilled artisan would look to the art to use such known blood glucose meters in the Brown apparatus. In other words, the skilled artisan would be motivated to use the Brown blood glucose meter as the specific type of blood glucose meter generally disclosed by Brown because Brown contemplates using known blood glucose meters. The skilled artisan would have reasonable expectation of success in using the Phillips et al. blood glucose meter in the Brown apparatus because it is predictable that such a blood glucose meter will still work in an apparatus that has a compartment for administering medicine such as insulin. (it is noted that Applicants' claimed

device is a combination of elements described as a package. Applicants' claim reads on the Brown apparatus comprising a compartment for holding medicine and an integrated measurement apparatus, including one in which the measurement apparatus is as disclosed by Phillips et al.)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in black ink, consisting of a stylized 'A' followed by a cursive 'L' and 'L'.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ann Y. Lam
Primary Patent Examiner
12/13/07